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Use of real-time clinical surveillance decision support software as a trigger tool for measuring adverse drug events

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Background

- ADEs have long been recognized as a major cause of morbidity and mortality for hospitalized patients.
- Incidence of ADEs vary in the literature depending on the definitions and methods of measurement.
- Conventional methods to quantify ADEs include voluntary reporting and retrospective medical record review. Studies have demonstrated this approach identified ≤ 1% and up to 40% of all ADEs, respectively.
- The purpose of this study is to evaluate if Sentri7®, Pharmacy OneSource (Bellevue, WA) a real-time, web-based, clinical surveillance software can be used to identify ADEs prospectively in community hospitals.

Objectives

- Determine if clinical surveillance software can help identify and prevent ADEs prospectively
- Examine the predictive value of the clinical surveillance software in capturing ADEs and potential ADEs

Patient Population

Study Design

- Observational pre-post study

Data Source and Study Population

- Data collected from 2 community hospitals:
  - ❑ Hospital A : small rural (50 – 100 beds), community based hospital located in central US
  - ❑ Hospital B: medium rural (100 – 300 beds), community based hospital located in southeast US

Inclusion Criteria

- Adult patients ≥ 18 years of age
- Experienced adverse drug event

Study Period

- Pre-period: Jun. to Oct. 2014 (5 months)
- Post-period: Dec. 2014 to Apr. 2015 (5 months)

Methods

Ten rules, "triggers" have been identified and programmed into the Sentri7® software tool at study sites to prospectively capture ADEs.

Table 1. ADE Surveillance Rules

Rule Name	Rule Description
ADE Allergic Reaction	Identify patients who received one time diphenhydramine for possible allergic reaction
Nephrotoxic Drugs Induced AKI	Identify patients on nephrotoxic agents and developed acute kidney injury (AKI)
Warfarin Induced INR Elevation Requiring Vitamin K Reversal	Identify patients previously/currently on warfarin with elevated INR requiring phytonadione reversal
Naloxone for Opioid Reversal	Identify patients previously/currently on opioid requiring naloxone for reversal
Drug Induced Hypoglycemia Reversal	Identify patients on insulin and/or oral hypoglycemic agents experiencing hypoglycemic episode requiring reversal
Drug Induced Hyperkalemia Reversal	Identify patients on agents that can elevate potassium level requiring reversal
Drug Induced Diarrhea	Identify patients on common diarrhea causative medications receiving antidiarrheal therapy
Drug Induced Thrombocytopenia	Identify patients common thrombocytopenia causative medications resulting in low platelet count
Antibiotic-associated Clostridium difficile Infection	Identify patients who were previously on antibiotics resulting in C. difficile colitis
INR Elevation Due to Warfarin Drug Interaction	Identify patients on warfarin concomitantly receiving medications that can interact with therapy leading to INR elevation

Figure 1A. Hospital A Baseline Voluntary Reported MV and ADR

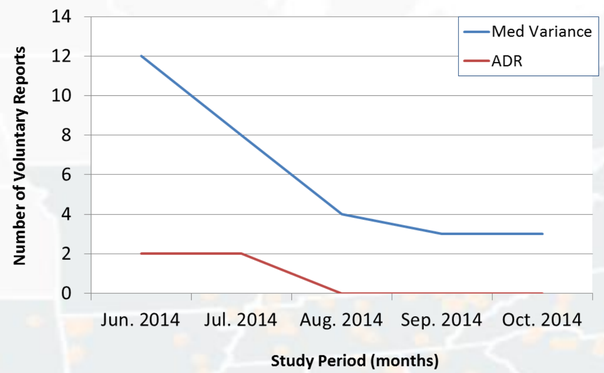
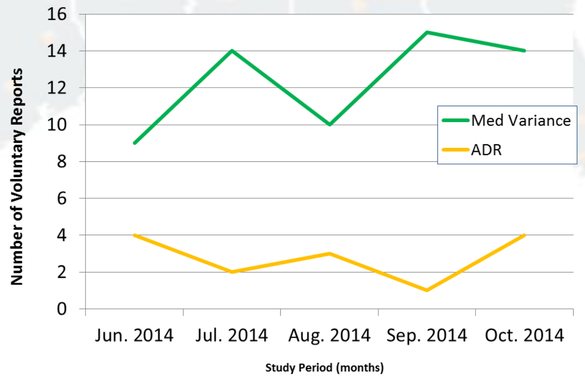


Figure 1B. Hospital B Baseline Voluntary Reported MV and ADR



- Figure 1A shows the number of voluntary reported ADEs in the pre-study period over 5 months at Hospital A.
- Figure 1B shows the number of voluntary reported ADEs in the pre-study period over 5 months at Hospital B.

Data Collection

- The following data will be collected through study period:
  - ❑ Patient demographics
  - ❑ Causative medication
  - ❑ Reaction to causative agent
  - ❑ Medication error type
  - ❑ Severity of reaction
  - ❑ Frequency and types of alerts produced
  - ❑ Frequency of alert yielding true ADEs
  - ❑ Number of patient days and admissions
  - ❑ Change in number of voluntary incident reports of ADEs

Case Identification

- Upon trigger alert, pharmacists will identify probability of a true adverse drug event using Naranjo's algorithm
- Pharmacists will then document interventions in the clinical surveillance software

Conclusion

Our study is expected to demonstrate:

- An increase number of voluntary report
- The use of voluntary reporting as the sole mechanism of ADE detection is associated with underreporting of events
- A real-time, clinical surveillance software is effective at identifying ADEs

Reference

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Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation. Yin Wong, the primary author is currently completing a fellowship at Wolters Kluwer Health, a medical content and software company.